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EXAMINER	
PORTER, RACHEL L	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/923,385	MICHELSON ET AL.	
	Examiner	Art Unit	
	Rachel L. Porter	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-15 and 129-151* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-15 and 129-151* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1. Claims 2-15 and 129-151 are pending. This communication is in response to the amendment filed 4/23/07.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 137 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 137 recites that the questionnaire recites "wherein said questionnaire information regarding at least one of inclusion criteria, exclusion criteria, and combinations thereof." Claim 137 is vague and indefinite because it is unclear how "at least *one* of" includes "combinations." For the purpose of applying art, the examiner will interpret the claim language to mean that the questionnaire includes at least one of inclusion criteria or exclusion criteria.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

> the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 2, 4,7,10-13 and 130-151 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldwin, Gary, "System makes it easier to link patients to clinical trials"(hereinafter Baldwin" in view of information available at the website of CenterWatch (hereinafter CenterWatch) and Brown (USPN 6,196,970).

As per claim 2, Baldwin discloses a method for recruiting a person to participate as a subject in a clinical study (i.e. link patients to clinical trial)(title and abstract), comprising the steps of:

(a) presenting one or more web pages that allow the person or a caregiver associated with the person to register with a database by submitting registration information to the database (i.e. AOR Securenet is a secure extranet ... patient information is entered online...)(page 2), wherein the registration information includes at least one disease condition of interest to the person, contact information, and permission information indicating whether the person or caregiver wishes to receive notice of one or more clinical studies (i.e. ... if fuzzy match is made, an email alert with online link to trial information is sent to patient's physician ... open to select users. Clinicians, drug companies and administrators ...)(page 2-3);

(b) automatically registering the person or caregiver with the database upon receipt of the registration and permission information (see entire article);

(c) after step (b), automatically determining, in accordance with the permission information and the registration information, whether to provide the person or caregiver with notice of a given clinical study associated with a disease condition of interest to the

person (i.e. ... if fuzzy match is made, an email alert with online link to trial information is sent to patient's physician ... open to select users. Clinicians, drug companies and administrators...)(pages 2-3);

(d) providing the person or caregiver notice of the given clinical study only if a determination is made in step (c) to provide such notice (i.e. ... if fuzzy match is made, an email alert with online link to trial information is sent to patient's physician... open to select users. Clinicians, drug companies and administrators ...)(pages 2-3);

Baldwin does not explicitly disclose

wherein the registration information includes at least a geographic location of the person.

However, CenterWatch discloses wherein the registration information includes at least a geographic location of the person (i.e. Patient Notification Service pages). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of Baldwin with the teaching of CenterWatch to include the collection of geographic location in the registration information of the person for the motivation of providing clinical trial matching information for patients and research professionals interested in information on and/or participating in clinical trials (CenterWatch Home Page).

Baldwin and CenterWatch in combination do not explicitly disclose

(e) automatically presenting a questionnaire associated with the given clinical study to the person or caregiver after step (d); and

(f) storing answers submitted by the person or caregiver in the database .

However, Baldwin does disclose that after the patient has enrolled in a trial, the online system manages additional data collection and reporting. (Baldwin: par. 25) Brown discloses automatically presenting a questionnaire associated with the given clinical study to the person or caregiver after step (d) (i.e. trial specific questions)(col. 4, lines 3-15—the subject responds to the protocol associated with the clinical trial (i.e. research trial), which includes questions). Brown also discloses storing answers submitted by the person or caregiver in the database (col. 6, lines 19-27, lines 43-44—subject responses are sent back to the server and stored on the database). At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Baldwin and CenterWatch in combination to present questionnaires associated with the given clinical trial to the person/subject (or caregiver) and to store the responses submitted by the person/subject a database. As suggested by Brown, one would have been motivated to include these features to facilitate the aggregation and analysis of data from remote sites. (Brown: col. 3, lines 7-8)

As per claim 4, Baldwin and CenterWatch do not explicitly disclose the method of claim 2, wherein the questionnaire includes criteria specific to a clinical study for determining whether the person is an eligible subject for the given clinical study.

Brown discloses a method the questionnaire includes criteria specific to a clinical study for determining whether the person is an eligible subject for the given clinical study. (col. 4, lines 29-39;col. 6, lines 19-27, lines 43-44) Brown discloses a method wherein protocol feedback (i.e. including questionnaire responses) allow researchers to

determine whether a subject or given population is responsive to the treatment in a study or if a new population should be targeted (i.e. new patients are eligible). At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art further modify the method of Baldwin and CenterWatch to include criteria within the questionnaire to determine whether the person is an eligible subject for the given clinical study. As suggested by Brown, one would have been motivated to include this feature to minimize fuzzy assessments made regarding a patients following a given a protocol, thereby imposing a more logical assessment upon subject assessment. (col. 4, lines 14-19)

As per claim 7, Baldwin discloses the method of claim 2, wherein the notice provided in step (d) is sent by electronic mail from a web site associated with the one or more web pages to an e-mail address of the person or caregiver (page 2).

As per claim 10, Baldwin does not explicitly disclose the method of claim 2, wherein a determination is made to provide the person or caregiver with the notice in step (c) in accordance with a geographic location of the given clinical study.

However, Baldwin does disclose wherein a determination is made to provide the person or caregiver with the notice in step (c) as discussed previously above. CenterWatch discloses providing notice of clinical studies in accordance with a geographic location of the given clinical study (CenterWatch Patient Notification service pages). It would have been obvious to one of ordinary skill in the art at the time of

Applicant's invention to include notice of clinical studies in accordance with a geographic location of the given clinical study as disclosed by CenterWatch within Baldwin for the motivation of providing clinical trial matching information for patients and research professionals interested in information on and/or participating in clinical trials (CenterWatch Home Page).

As per claim 11, Baldwin discloses the method of claim 2, wherein in step (c) a determination is made not to provide the person or caregiver with notice of the given clinical study (i.e. fuzzy matches. The Examiner interprets this feature to read on clinical trials that the person or caregiver does not match)(page 2).

As per claim 12, Baldwin discloses the method of claim 2, wherein in step (a) the registration information includes whether the person is interested in clinical study information, whether the person is interested in new medical therapies, or whether the person is interested in participating in clinical studies (page 2).

As per claim 13, Baldwin does not explicitly disclose the method of claim 2, wherein a determination is made to provide the person or caregiver with the notice in step (c) in accordance with a geographic location of an investigator associated with the study.

However, Baldwin discloses wherein a determination is made to provide the person or caregiver with the notice in step (c). CenterWatch discloses providing a list of

clinical study(ies) in accordance with a geographic location of a clinical study as discussed previously above (the Examiner interprets the geographic determination limitation to include the geographic location of the clinical trial the investigator is associated with). It would have been obvious to one of ordinary skill at the time of Applicant's invention to include the geographic location matching of CenterWatch with the determination step of Baldwin for the motivation of providing clinical trial matching information for patients and research professionals interested in information on and/or participating in clinical trials (CenterWatch Home Page).

As to claims 130-136, Baldwin, CenterWatch, and Brown disclose the method of claim 2 as explained in the rejection of claim 2. Baldwin and CenterWatch do not explicitly disclose that questionnaire is a pre-examination questionnaire (e.g. screening questionnaire; pre-screening questionnaire)

Brown discloses a method wherein questionnaires are administered and data are collected at various points throughout research trial process (col. 4, lines 3-18; Figure 2b) Brown discloses that the research protocol maybe be modified, non-responders may be identified, and new subgroups within the subjects may be identified for alternate or different testing with different parameters (col. 4, lines 26-37) As such, the questionnaires provided to the patients may function as screening, pre-screening, and pre-examination questionnaires in identifying those who are not eligible (i.e. responding poorly to the protocol) or identifying those who will participate well or poorly in the trial (non-responsive or responsive to the questionnaires)

Brown further discloses a method the questionnaire wherein criteria specific to a clinical study for determining whether the person is an eligible subject for the given clinical study. (col. 4, lines 29-39;col. 6, lines 19-27, lines 43-44) Brown discloses a method wherein protocol feedback (i.e. including questionnaire responses) allow researchers to determine whether a subject or given population is responsive to the treatment in a study or if a new population should be targeted (i.e. new patients are eligible). At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art further modify the method of Baldwin and CenterWatch to include criteria within the questionnaire to determine whether the person is an eligible subject for the given clinical study. As suggested by Brown, one would have been motivated to include this feature to minimize fuzzy assessments made regarding a patients following a given a protocol, thereby imposing a more logical assessment upon subject assessment. (col. 4, lines 14-19)

As to claim 137, Baldwin, CenterWatch, and Brown disclose the method of claim 2 as explained in the rejection of claim 2. Baldwin does not expressly disclose that the questionnaire included inclusion or exclusion criteria. CenterWatch discloses a questionnaire that includes inclusion or exclusion criteria. (The Patient Notification pages ask the patients about their geographic location limits, whether they would like to know about drugs recently approved by the FDA; medical areas of interest—page 12 of website packet) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Baldwin with the teaching of CenterWatch to include exclusion or inclusion criteria on a questionnaire. One would

have been motivated to include this feature to avoid wasting resources pursuing individuals who may no longer be interested in participating in a trial.

As to claims 138 and 150, the claims are substantially similar in scope to claim 131. As such, claims 138 and 150 are rejected for the reasons provided in the rejections of claims 2, 130, and 131, and incorporated herein.

As to claim 139 and 140, the limitations of the present claims are addressed by the rejection of claim 138.

As to claims 141-148, the claims are similar in scope to claims 130-137 and are rejected on the same basis.

As to claims 149 and 151, the limitations of the present claims are addressed by the rejection of claim 138.

6. Claims 3 and 129 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldwin, CenterWatch and Brown as applied to claim 2 above, and further in view of "TVisions wins Top Web Externet Award; Recognized for Creative, Life-Saving Site" (hereinafter TVisions).

As per claim 3, Baldwin, CenterWatch, and Brown do not explicitly disclose the method of claim 2, further comprising the step of:

(g) accessing the answers to the questionnaire along with other information in the database to determine whether the person qualifies to participate as a subject in a clinical study different from the given clinical study after step (f).

However, TVisions discloses accessing the answers to the questionnaire along with other information in the database to determine whether the person qualifies to participate as a subject in a clinical study different from the given clinical study after step (f) (i.e. additions and updates to the patient profile database and the clinical trial databases activates the SecureNet Trial Matching System ...)(page 2). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include accessing the answers to the questionnaire along with other information in the database to determine whether the person qualifies to participate as a subject in a clinical study different from the given clinical study after step (f) as disclosed by TVisions within Baldwin, CenterWatch and Brown for the motivation of alerting physicians within seconds of possible matches of their patients with available or new clinical trials (page 2, second paragraph).

As per claim 129, the limitations of claim 129 are substantially similarly to claim 2 with the exception of "step e." Baldwin, CenterWatch and Brown disclose a method for recruiting a person to participate as a subject in a clinical study as explained in the rejection of claim 2 above.

Baldwin, CenterWatch, Brown do not explicitly disclose

(e) allowing the person or caregiver the opportunity to amend the registration information in the database during a subsequent visit to the web site.

However, TVisions allowing the person or caregiver the opportunity to amend the registration information in the database during a subsequent visit to the web site (i.e.

additions and updates are to the patient profile database ...)(page 2). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include storing answers submitted by the person or caregiver in the database as disclosed by TVisions for the motivation of alerting physicians within seconds of possible matches of their patients with available clinical trials and new clinical trials (page 2, second paragraph).

7. Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldwin, CenterWatch and Brown, as applied to claim 2, and in further view of Schmidt et al (USPN 6,839,687)

As per claim 5, Baldwin and CenterWatch a method for registering caregivers or individuals online and via the World Wide Web for clinical trials, as explained in the rejection of claim 2. Brown further discloses automatically generating questionnaires and storing data for a person or caregiver on a database, as explained in the rejection claim 2.

However, Baldwin, Brown and CenterWatch do not explicitly disclose the method of claim 2, wherein steps (a) and (b) are performed during a registration visit by the person or caregiver to a web site associated with the one or more web pages, and step (g) includes notifying the person or caregiver of the given clinical study during a current or subsequent visit of the person or caregiver to the web site (page 2).

Schmidt discloses a method wherein steps (a) and (b) are performed during a registration visit by the person or caregiver to a web site associated with the one or

more web pages, (col. 2, lines 1-21, lines 27-34—information collection, eligibility determination and notification; col. 3, line 24-25—communication through Internet technology) and step (g) includes notifying the person or caregiver of the given clinical study during a current or subsequent visit of the person or caregiver to the web site (col. 4, lines 54-67). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the method of Baldwin, Brown and CenterWatch in combination with the teaching of Schmidt to have steps (a) and (b) performed during a registration visit by the person or caregiver to a web site associated with the one or more web pages, and step (g) include notifying the person or caregiver of the given clinical study during a current or subsequent visit of the person or caregiver to the web site. As suggested by Schmidt, one would have been motivated to include these features to provide method and system for conducting medical studies which enables a simpler and more effective completion of the medical studies (col. 1, lines 65-67)

As per claim 6, Baldwin discloses the method of claim 5, wherein step (d) further includes providing a listing of information associated with the given clinical study in a personal library associated with the person or caregiver on the web site (par. 10- 14).

8. Claims 8-9, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldwin, CenterWatch, and Brown, as applied to claim 2, and in further view of Admitted Prior Art (in accordance with MPEP 2144.03 (C)).

As to claims 8-9, Baldwin, CenterWatch, and Brown in combination do not explicitly disclose the method of claim 2, wherein the notice provided in step (d) is sent

by "regular" mail or telephone to the person or caregiver. However, it is submitted that at time of the applicant's invention, the telephone and "paper mail" (i.e. snail mail) were old and well-known means of communicating requested information or notifications to individuals. At the time of the applicant's invention it would have been obvious to one of ordinary skill in the art to modify the method of Baldwin, CenterWatch, and Brown in combination to have the notice of step (d) sent by regular mail or telephone to the person or caregiver. As suggested by Brown, one would have been motivated to include these features to facilitate the aggregation and analysis of data from remote sites. (Brown: col. 3, lines 7-8)

As per claim 14, Baldwin, CenterWatch, and Brown teach the method of claim 2 as explained in the rejection of claim 2, but do not explicitly disclose the method of claim 2, wherein the answers submitted by the person or caregiver are provided by telephone, regular mail, facsimile, and other off-line sources. However, the Examiner takes official notice that at the time of the applicant's invention it was well known in the art to provide information by telephone, mail, fax, or other "offline sources" such as hand delivery. It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention it would have been obvious to one of ordinary skill in the art modify the system of Baldwin, CenterWatch and Brown in combination to allow the person or caregivers to communicate answers by alternate means. One would have been motivated to include the alternatives to provide the customer with customer preferred delivery methods particularly with highly sensitive information.

9. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baldwin, CenterWatch and Brown as applied to claim 2 above, and further in view of Larkin, Marilynn, "Physicians accelerate onto the Internet" (hereinafter Larkin).

As per claim 15, Baldwin and CenterWatch do not explicitly disclose the method of claim 2, wherein the step of automatically determining further includes reference to genetic sequence information associated with a person registered in the database.

However, Larkin discloses clinical studies directed to particular genetic sequences and using online recruitment (page 2). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to include the online patient recruitment of clinical studies for genetic studies within the Baldwin, CenterWatch and Brown in the method for the motivation of speeding up patient recruitment (i.e. within 6 months of the site's inauguration, 127 eligible woman ... By contrast, it took 4 years to recruit 395 volunteers with traditional methods ...)(see abstract and page 2)

Response to Arguments

10. Applicant's arguments filed 4/23/07 have been fully considered but they are not persuasive.

(A) Applicant argues that the combination of Baldwin, Centerwatch, and Brown is impermissible. In particular, Applicant argues that the Brown questionnaire is not applicable because it "could not possibly be presented automatically and after step (d)"

and that the questions in Brown occur "only if" the person has enrolled in the clinical study.

In response, it must be noted that as currently recited, steps (d), (e), are (f) are conditional steps, which are apparently not required for the method of claim 2 to occur. In other words, step (d) recites " providing the person or caregiver notice of the given clinical study **only if a determination is made in step (c) to provide such notice**..." Therefore, if no determination is made to provide notification, as indicated by the conditional language, step (d) does not occur. Likewise, the "automatic presentation of a questionnaire" in step (e) is apparently dependent upon the occurrence of step(d), since the language specifically recites that the step must occur "after step (d)." Furthermore, there are "no answers submitted by the person or caregiver" to be stored in a database, given the alternative and conditional language of step(d).

Moreover, in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

The Brown reference was relied upon to disclose presenting a questionnaire associated with the given clinical study to the person or caregiver after step (d) (i.e. trial specific questions)(col. 4, lines 3-15—the subject responds to the protocol associated with the clinical trial (i.e. research trial).. Brown also discloses storing answers submitted by the person or caregiver in the database (col. 6, lines 19-27, lines 43-44—

subject responses are sent back to the server and stored on the database). Therefore, Brown, in combination with the Baldwin and Centerwatch references addresses the limitations of claim 2.

(B) Applicant argues that Baldwin never mentions "registering any data" further argues that there is no indication that the patient or caregiver is ever "register" in the AOR database. Applicant further argues that Baldwin does not disclose "that the registration information includes...at least one disease condition of interest to the person, contact information, and permission information indicating whether the person or caregiver wishes to receive notice or one or more clinical studies...."

In response, the Examiner disagrees with Applicant's interpretation of the prior art references. It is respectfully submitted that the entire Baldwin reference discloses a system for registering physicians and interested persons onto a database to be matched for clinical trials. On page 2, par. 6, Baldwin discloses that the database serves 340 member physicians. Baldwin also discloses, the registration process for other persons (e.g. patients) on pages 2-3. For example, in par. 11-15 of page 2, Baldwin discloses that information including age, sex, type of cancer (e.g. disease of interest), and type of treatment is entered online.

The ability of the system to contact/notify the physician through and e-mail alert, then (conditionally, if specific criteria) the patient based upon the results of the fuzzy match process obviates the presence of contact information and the "permission to notify." Moreover, the test for obviousness is not that the claimed invention must be

expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

(C) Applicant argues the Baldwin, Centerwatch, and Brown do not provide "the requisite motivation to combine and/or modify their teachings to arrive at invention recited in claim 2." Applicant further argues that the combined systems would not work.

In response *KSR* forecloses Appellant's argument that a *specific* teaching, suggestion or motivation is required for a finding of obviousness. See *Ex parte Smith* 83 USPQ2d 1509 *(citing KSR*, 127 S.Ct. at 1741, 82 USPQ2d at 1396)

Moreover, the examiner has provided appropriate rationale to support the combinations and to support the holding of obviousness in each of the rejected claims.

Furthermore, in response to applicant's argument that the database of Baldwin is inoperable with the Centerwatch system, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

In addition, Centerwatch provides information regarding both physicians/research professionals and patients as does the database in the Baldwin reference. Therefore, it is unclear to the Examiner, how either reference may be precluded.

(D) Applicant's assert that the archived webpages of Centerwatch do not qualify as prior art.

In response, the URL of the web.archive.org/web includes the date and time upon which the target page was archived. In other words, a URL of: web.archive.org/web/**19981205034643**/http://www.centerwatch.com/ correlates to the archiving YYYYMMDDhhmmss of the target URL: www centerwatch.com. (Dec. 5, 1998). As such, the Centerwatch webpages would qualify as prior art, since it is before applicant's priority date. An explanation of the web archive URL has been attached for Applicant's convenience.

(E) Applicant argues that the prior art, particularly Brown, fails to disclose a method for determining whether a person is eligible for a given clinical study, and does not meet the limitations of claim 4.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Brown discloses a method and system in which questions/ a questionnaire includes criteria specific to a clinical study for determining whether the person is an eligible subject for the given clinical study. (col. 4, lines 29-39) Brown discloses a

method wherein protocol feedback (i.e. including questionnaire responses) allow researchers to determine whether a subject or given population is responsive to the treatment in a study or if a new population should be targeted. Furthermore, col. 4, lines 29-37 of Brown states that the incoming data, which includes patient responses to questions, allows the reviewer to identify specific subgroups among a population, initiate new lines of inquiry and test new sub hypotheses (i.e. the patients are eligible/subgroups are targeted).

(F) Applicant argues that the limitations of claim 7 are not addressed because it is dependent from claim 2, and the combination of references applied to claim 2 is improper.

In response, Baldwin discloses the method of claim 2, wherein the notice provided in step (d) is sent by electronic mail from a web site associated with the one or more web pages to an e-mail address of the person or caregiver (page 2), as recited in claim 7. Moreover, the additional arguments regarding claim 2 are addressed by par. 10 (A-E) of the present Office Action.

(G) Applicant argues that Centerwatch fails to disclose the use of geographic information in the notification process (i.e. a determination to provide notice to a person or caregiver in accordance a geographic location of the given clinical study...)

CenterWatch discloses providing notice of clinical studies in accordance with a geographic location of the given clinical study (CenterWatch Patient Notification service

pages). Centerwatch also specifically asks the patient for their geographic region of interest.

Again, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Furthermore *KSR* forecloses Appellant's argument that a *specific* teaching, suggestion or motivation is required for a finding of obviousness. See *Ex parte Smith* 83 USPQ2d 1509 *(citing KSR*, 127 S.Ct. at 1741, 82 USPQ2d at 1396) The examiner has provided appropriate rationale to support the combinations and to support the holding of obviousness in the rejected claim.

(H) Applicant argues that Baldwin does not disclose the decision not to provide information. (claim 11)

It is respectfully submitted that, as claimed by the applicant, Baldwin provides conditional notification. (page 2, par .12-15: alert to the patient is provided to the patient only if participation is warranted.) The additional arguments regarding claim 11 are addressed by par. 10 (A-E) of the present Office Action.

(I) Applicant argues that Baldwin "makes no mention of either the caregiver and/or the patient providing whether the person is interested in clinical study information, whether the person is interested in new medical therapies, or whether the person is interested in participated in clinical studies."

In response, it is respectfully submitted that the Baldwin reference, "System Makes It Easier to Link Patients to Clinical Trials," discloses a system and method wherein the registration information includes whether the person is interested in clinical study information, whether the person is interested in new medical therapies, or whether the person is interested in participating in clinical studies (page 2). In particular, page 2, par. 6-16 explain that physicians are members of the database, and patient information (demographics and cancer type, and treatment) is added to the system for the purpose of matching physicians/caregivers and patients in clinical studies.

The additional arguments regarding claim 11 are addressed by par. 10 (A-E) of the present Office Action.

(J) Applicant argues that Centerwatch fails to disclose the use of geographic information in the notification process (i.e. a determination to provide notice to a person or caregiver in accordance a geographic location of the given clinical study...) (claim 13)

CenterWatch discloses providing notice of clinical studies in accordance with a geographic location of the given clinical study (CenterWatch Patient Notification service pages). Centerwatch also specifically asks the patient for their geographic region of interest. The additional arguments regarding claim 13 are addressed by par. 10 (A-E) of the present Office Action.

(K) Applicant argues that prior art fails to address the claim limitations of 130-136.

In response, the Examiner submits that the arguments on pages 21-23 of the response are addressed by par. 10 (A-E) of the present Office Action.

(L) Applicant argues there is no suggestion to combine the references for claim 137.

Again, *KSR* forecloses Appellant's argument that a *specific* teaching, suggestion or motivation is required for a finding of obviousness. See *Ex parte Smith* 83 USPQ2d 1509 *(citing KSR*, 127 S.Ct. at 1741, 82 USPQ2d at 1396)

Moreover, the examiner has provided appropriate rationale to support the combinations and to support the holding of obviousness in claim 137, using motivation provided from a cited reference.

(M) Applicant's arguments regarding claims 138-151 amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references and fails to explain why independent 138-140 and 149-151(and their dependents claims) are not obvious over claim 2 and its dependents. The additional arguments regarding claim these are addressed by par. 10 (A-E) of the present Office Action.

(N) Applicant argues that "TVisions.." does not disclose accessing answers to a questionnaire to determine if a patient qualifies as a subject in a different clinical trial.

In response, as explained in the rejection of claim 3, TVisions discloses additions and updates to the patient profile database and the clinical trial databases activates the SecureNet Trial Matching System ...)(page 2) (accessing the answers to the questionnaire along with other information in the database to determine whether the person qualifies to participate as a subject in a clinical study different from the given clinical study after step (f))

In particular, page 2, par. 10-12, describes that the patient's disease state and willingness to participate is accessed and constantly reconsidered as new trials open and close. The computer "continually scans for new matches..." (par. 12)

(O) Applicant's argue that "TVisions" does not disclose "allowing the person or caregiver the opportunity to amend the registration information during a subsequent visit to the web site..."

On page 2, par. 10, TVisions discloses "When a patient's disease status changes...a participating physician quickly updates records, and the system searches for an open, appropriate, trial match..." (i.e. allowing the person or caregiver the opportunity to amend the registration information in the database during a subsequent visit to the web site (i.e. additions and updates are to the patient profile database ...)(page 2).

Furthermore, it is respectfully submitted that the breadth and tentative nature of the current claim language provides no real outcome to the step. In other words, there is no positive recitation of an action being performed, by merely "allowing the person or caregiver the opportunity to ..." perform the step. The mere presentation of the web page, as recited in step (a) allows the user the opportunity to perform the step. No data entry or updating is required to meet the limitations of the claim language.

The additional arguments regarding claim 129 are addressed by par. 10 (A-E) of the present Office Action.

(P) Applicant argues that the prior art fails to address the limitations of claims 5-6.

Again, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

As per claim 5, it is noted that the current claim language requires the notification step may occur during **a current or subsequent visit** of **the person or the caregiver** to the website. Schmidt discloses a method wherein steps (a) and (b) are performed during a registration visit by the person or caregiver to a web site associated with the one or more web pages, (col. 2, lines 1-21, lines 27-34—information collection, eligibility determination and notification; col. 3, line 24-25—communication through Internet technology) and step (g) includes notifying the person or caregiver of the given clinical study during a current or subsequent visit of the person or caregiver to the web site (col. 4, lines 54-67). Therefore, Schmidt in combination with the additional references addresses the claim limitations.

As per claim 6, Baldwin discloses the method of claim 5, wherein step (d) further includes providing a listing of information associated with the given clinical study in a personal library associated with the person or caregiver on the web site (par. 10- 14- citation clarification of Baldwin has been provided). The Baldwin reference provides information on the clinical trial with the notification step.

(Q) On pages 32-34, applicant argues the motivation to combine Brown, with the other references, particularly for claims 8-9.

KSR forecloses Appellant's argument that a *specific* teaching, suggestion or motivation is required for a finding of obviousness. See *Ex parte Smith* 83 USPQ2d 1509 *(citing KSR*, 127 S.Ct. at 1741, 82 USPQ2d at 1396)

Furthermore, the examiner has provided appropriate rationale to support the combinations and to support the holding of obviousness in the rejected claim. The Examiner took Official Notice that at time of the applicant's invention, the telephone and "paper mail" (i.e. snail mail) were old and well-known means of communicating requested information or notifications to individuals. Applicant failed properly traverse the noted the fact that these were old and well-known means of communicating requested information or notifications to individuals. Therefore, it is taken as admitted prior art in accordance with MPEP 2144.03 (C)

Moreover, despite applicant's claim that Brown teaches away from the claimed invention, at the time of the applicant's invention it would have been obvious to one of ordinary skill in the art to modify the method of Baldwin, CenterWatch, and Brown in combination, to include the various well-known recited means of communication (to have the notice of step (d) sent by regular mail or telephone to the person or caregiver) with the motivation of facilitating the aggregation and analysis of data from remote sites. (Brown: col. 3, lines 7-8: states that this is a common logistical problem which must be addressed in clinical trials.)

(R) Applicant argues that the combination and motivation used in the rejection of claim 14 is inappropriate.

The Examiner took Official Notice that it was well known in the art to provide information by telephone, mail, fax, or other "offline sources" such as hand delivery. Applicant failed properly traverse the noted the fact that these were old and well-known means of providing information . Therefore, it is taken as admitted prior art in accordance with MPEP 2144.03 (C)

KSR forecloses Appellant's argument that a *specific* teaching, suggestion or motivation is required for a finding of obviousness. See *Ex parte Smith* 83 USPQ2d 1509 *(citing KSR*, 127 S.Ct. at 1741, 82 USPQ2d at 1396).

Furthermore, the examiner has provided appropriate rationale to support the combinations and to support the holding of obviousness in the rejected claim.

It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention it would have been obvious to one of ordinary skill in the art modify the system of Baldwin, CenterWatch and Brown in combination to allow the person or caregivers to communicate answers by alternate means (i.e. by telephone, mail, fax, or other "offline sources" such as hand delivery). One would have been motivated to include the alternatives to provide the customer with customer-preferred delivery methods, particularly with highly sensitive information.

(S) Applicant argues that the prior art, Larkin, fails to address the limitations of claim 15.

In response, it is respectfully submitted that applicants do not realize the breadth of the current claim language. Applicant's arguments suggest applicants are attempting

to claim a system/method wherein a screening of the perspective candidate is done based upon known gene sequence before individuals are determined to be appropriate for the study.

However, the current claim language merely requires a ***reference*** to genetic sequence ***information associated*** with ***a person*** registered in the database (not the candidate). In other words the current claim does not require gene sequence at all. The recruitment and acceptance of family members for family members and sib-pair studies, as disclosed by Larkin (par. 5-11), addresses the limitations of claim 15, as currently claimed.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure

- McAlindon et al (US 7,251,609) discloses a method and system for recruiting subjects for a clinical trial over the Internet.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel L. Porter whose telephone number is (571) 272-6775. The examiner can normally be reached on M-F, 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RP

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